

## **REMARKS**

### **I. Response to Restriction Requirement**

In the Office Action, the Examiner has issued a Restriction Requirement, requiring election of one of the five groups identified by the Examiner at page 2 of the Office Action.

Applicants hereby elect, with traverse, the Group identified by the Examiner as Group I, claims 37-66 and 73-84, drawn to low dose tablets.

Applicants respectfully traverse the Restriction Requirement as set forth by the Examiner. Moreover, Applicants respectfully assert that Groups I - V relate to a single inventive concept and should properly be examined together. Further, Applicants submit that Groups I -V are closely related and that a proper search of any of the claims should, by necessity, require a proper search of the others. Thus, Applicants submit that all of the claims can be searched simultaneously, and that a duplicative search, with possibly inconsistent results, may occur if the restriction requirement is maintained.

Applicants submit that any nominal burden placed upon the Examiner to search accordingly to determine the art relevant to Applicants' overall invention is significantly outweighed by the public's interest in not having to obtain and study many separate patents in order to have available all of the issued patent claims covering Applicants' invention. The alternative is to proceed with the filing of numerous applications, each consisting of generally the same disclosure, and each being subjected to essentially the same search, perhaps by different Examiners on different occasions. This process would place an unnecessary burden on both the Patent and Trademark Office and on the Applicants. In the interest of economy, for the Office, for the public-at-large, and for Applicants, reconsideration and withdrawal of the Restriction Requirement are requested.

### **II. Response to Election of Species Requirement**

In addition, in the event that Group I is elected in response to the Restriction Requirement, the Examiner has further required election for prosecution on the merits of one species each from the four categories set forth at page 4 of the Office Action.

In response to the Election of Species Requirement, Applicants hereby elect, for the purposes of searching only, the following species:

- gums of natural or microbial origin, for example xanthan gum as a specific polymer (see page 19, line 36, to page 20, line 5 of the present specification);

- a glycerol fatty acid derivative;
- polymers derived from methacrylic acid as film-coating agent; and
- analgesics as active principle.

In making the species election, Applicants understand that the Office will follow the procedure set forth in M.P.E.P. § 809.02, which provides for a complete action on the merits of all claims readable on the elected species, and in M.P.E.P. § 803.02, whereby on the finding of allowable species, examination will continue with the non-elected species until all species have been examined or a non-allowable species is found.

With regard to the active principle and the film-coating agent, Applicants note that the present claims are directed to a new type of low-dose tablets which can be applied with any active principle. In addition, the film-coating agents are selected depending on the active principle, as follows:

- the coating has to be compatible with the active principle;
- the coating has to be stable during the phase of product stabilization; and
- the coating has to guarantee the dissolution profile corresponding to the expected release profile.

Thus, the selection of the film-coating agent is carried out by one skilled in the art depending on the expected tablet.

**CONCLUSION**

The response to the Restriction and Election of Species Requirements has been made without prejudice or disclaimer to any of the non-elected subject matter. Applicants expressly reserve the right to file one or more continuation and/or divisional applications directed to any of the non-elected subject matter.

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

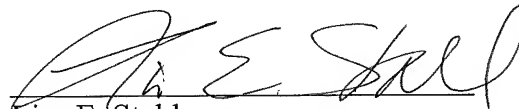
In the event that there are any questions related to this response, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney at the below-listed telephone number concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

Date: September 17, 2009

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